REMARKS

Claims 23 to 38 are pending in the application. No claims have been amended or canceled, and no new claims have been added, herein.

Applicants respectfully request reconsideration of the rejections of record in view of the following remarks.

Claim Objections

A. Claim 24 has been objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of claim 23. The Office asserts that since claims 23 and 24 differ only in their preambles, and have the same method steps, the claims are substantial duplicates. Applicants respectfully traverse the objection because it is well-established that a preamble may serve as a claim limitation,[1] and, accordingly, claims that differ only in their preambles are not necessarily substantial duplicates.

The preamble of claim 23 recites a method of enhancing the circulating half life of arginine deiminase and the preamble of claim 24 recites a method of enhancing the tumoricidal activity of arginine deiminase. If the preambles of each claim were accorded patentable weight, that is, if the preambles were considered to be limitations of each claim, the scope of the two claims would likely differ. Accordingly, if the claims were part of an issued patent, the extent of the patentee's right to exclude might be different for each claim. Put another way, the scope of protection afforded to the patentee by present claims 23 and 24, assuming they were to issue as part of a patent, would not *necessarily* be the same if the preambles of each claim were considered to be claim limitations. Applicants accordingly submit that claims 23 and 24 are thus not substantial duplicates, and respectfully request withdrawal of the objection.

B. Claim 35 has been objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of claim 25. The Office asserts that since claims 35 and 25 differ only in their preambles, and have the same method steps, the claims are substantial duplicates. Applicants respectfully traverse the objection because it is well-established that a preamble may serve as

[1] *Catalina Mktg. Int'l, Inc. v. Coolsavings Com., Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).

a claim limitation,[2] and, accordingly, claims that differ only in their preambles are not necessarily substantial duplicates.

The preamble of claim 35 recites a method of treating and inhibiting metastases in a patient and the preamble of claim 25 recites a method of treating a tumor in a patient. If the preambles of each claim were accorded patentable weight, that is, if the preambles were considered to be limitations of each claim, the scope of the two claims would likely differ. Accordingly, if the claims were part of an issued patent, the extent of the patentee's right to exclude might be different for each claim. Put another way, the scope of protection afforded to the patentee by present claims 35 and 25, assuming they were to issue as part of a patent, would not *necessarily* be the same if the preambles of each claim were considered to be claim limitations. Applicants accordingly submit that claims 35 and 25 are thus not substantial duplicates, and respectfully request withdrawal of the objection.

Alleged Indefiniteness

Claims 23 to 38 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. The preamble of claim 23 recites a method of enhancing the circulating half life of arginine deiminase and the preamble of claim 24 recites a method of enhancing the tumoricidal activity of arginine deiminase. The Office asserts that claims 23 and 24 are confusing because, since the claims have the same method steps and differ only in their preambles, it is "not seen how the same method can enhance circulating half-life without enhancing tumoricidal activity, or the converse."[3] Similarly, the preamble of claim 35 recites a method of treating and inhibiting metastases in a patient and the preamble of claim 25 recites a method of treating a tumor in a patient. The Office asserts that "it is not seen how the method of claim 25 that has the same steps as the method of claim 35 can treat a tumor and not treat and inhibit metastases…or the converse."[4] Applicants respectfully traverse the rejection because those skilled in the art could readily determine the scope of claims 23, 24, 35, and 25, which is all that the second paragraph of § 112 requires.

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[2] *Catalina Mktg. Int'l, Inc. v. Coolsavings Com., Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).
[3] Office action dated October 10, 2006, page 3.
[4] *Id.* at pages 3-4.

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 [second paragraph] demands no more." *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). Definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *In re Moore*, 439 F.2d 1232, 1235 (C.C.P.A. 1971).

Those skilled in the art could readily determine the scope of claims 23, 24, 35, and 25 when the claims are read in light of the specification. Accordingly, regardless of whether the subject matter of claims 23 and 24 is mutually exclusive or overlaps to some extent, and regardless of whether the subject matter of claims 35 and 25 is also mutually exclusive or overlaps to some extent, those skilled in the art could readily determine the metes and bounds of each claim. The claims therefore meet the requirements of 35 U.S.C. § 112, second paragraph, and applicants accordingly, respectfully request withdrawal of the rejection.

Alleged Double Patenting

A. Claims 23 to 28 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1 to 14 of U.S. patent number 6,737,259 ("the 259 patent"). Applicants respectfully traverse the rejection because 35 U.S.C. § 121 prohibits the Patent Office from using the 259 patent as the basis of a double patenting rejection against the present application.

The third sentence of 35 U.S.C. § 121 prohibits the use of a patent issuing on an application in which a requirement for restriction was made as a reference against a divisional of that application. Since a requirement for restriction was made during prosecution of the application that led to the 259 patent,[5] and since the present application is a divisional of that application, the Patent Office cannot use the 259 patent as a reference against the present

[5] See the Office action dated December 13, 2001.

application. The rejection for double patent based on the 259 patent is therefore improper, and applicants accordingly, respectfully request withdrawal thereof.

B. Claims 23 to 38 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1 to 22 of U.S. patent number 6,183,738. Although applicants question whether there has been an adequate showing that those of ordinary skill in the art would have found the cited claims to have been obvious in view of the claims of the referenced patent, they nonetheless submit herewith the requested terminal disclaimer. This is being done solely in an attempt to advance prosecution of the present patent application, and should not be construed to constitute an acknowledgment of obviousness or any other substantive relationship among the involved patent claims.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office action of record. Accordingly, an early and favorable action is respectfully requested.

Respectfully submitted,

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